

Remarks

Claims 1-34 and 44-48 remain pending in the present application. Claims 35-43 were previously cancelled. Claims 1, 2, 3, 8 and 33 have been amended. Claims 1-3 and 33 have been amended to remove the short hand references to activity (A) and activity (B) in the claims. Instead, these claims now recite the full antecedent for the intended activities used in the ratios. Step (iv) of claim 33 also is amended to replace the term “comparing” with a more appropriate word “determining” given the overall meaning of this step. Claim 8 has been amended to replace the phrase “obtention of” with the phrase “step of obtaining.” Applicants do not believe the intended meaning has changed, but the latter language has been suggested by the Examiner and accepted by applicants. Applicants do not believe any of these amendments introduce new matter into the application. Applicants respectfully request reconsideration and allowance of the claims in light of the following remarks.

The Office Action objects to the title as not being descriptive. While applicants believe the original title accurately captured the nature of the invention, they have nonetheless amended the title as suggested by the Examiner.

All of the claims have been rejected as being indefinite under 35 U.S.C. 112, para. 2. Applicants respectfully traverse this rejection.

In claims 1-3, the Office Action indicates that the meanings of (A) and (B) are not clear. Applicants have amended the claims to recite expressly what was previously intended by the shorthand references to (A) and (B) in the claims. With these amendments, the meaning of the claims is definite.

Referencing claim 8, the Office Action also states that the meaning of “obtention” was not clear. While applicants do not agree with this position, to advance prosecution Applicants have replaced the offending language with the clear phrase “step of obtaining.” Any perceived indefiniteness with the word “obtention” has been corrected.

All of the pending claims also stand rejected as being unpatentable (obvious) under 35 U.S.C. 103(a) over the combination of Kahane et al., (FEMS Microbiology Letters 1978;3:143-145) (hereafter “Kahane”) in view of Ito et al., (Analytical Sciences 2003;19:105-109) (hereafter “Ito”). This rejection is respectfully traversed.

The claims are directed to detecting the presence of contaminating *mycoplasma* in a sample. By using the terms “contaminating,” “contaminated,” or “contamination” in the claims in connection with *mycoplasma*, it is understood that the sample is one in which it is not known whether or not it contains any *mycoplasma*. Claim 32 recites a method for treating a cell culture to remove the *mycoplasma* contamination. Claim 33 specifically requires the use of a bioluminescent reaction in the detecting or measurement step.

The primary reference, Kahane, presents the results of a study aimed at determining whether (assessing the hypothesis that) acetate kinase (AK) acts as a supplier of ATP in *mycoplasma* as it does in anaerobic bacteria. In this regard, Kahane thus describes a method for the isolation and the analysis of AK. The reference obtains a pure preparation of AK from a known source, *A. laidlawii*. Thus, the organism was specifically cultured for producing the enzyme which was purified therefrom for analysis.

Pointedly, Kahane has no need to analyze any particular sample to detect whether *mycoplasma* is present in the sample. Rather, Kahane specifically cultured an organism

known to be a source of the enzyme for the sole purpose of preparing a purified preparation of the enzyme for analysis simply to test the hypothesis on the role played by AK. Indeed, the Office Action acknowledges that Kahane does not teach the detection of *mycoplasma* in cell culture (see page 4, lines 3-4 of the Office Action).

As the secondary reference, the Office Action relies on Ito. Ito relates to a bioluminescent approach for simultaneously assessing acetate kinase (AK) and pyruvate phosphate dikinase (PPDK) activities. In particular, Ito uses acetate kinase activity as one of the enzymatic reporters in a tandem immunoassay for unrelated antigens (*e.g.*, for assaying insulin and C-peptide in the same sample). Ito used PPDK from *Microbispora rosea subsp. Aerata* and AK from *B. stearrowthermophilus*. Nothing in Ito links the acetate kinase to *mycoplasma*.

While we question whether, in the absence of impermissible hindsight, a skilled worker would ever consider Ito in combination with Kahane, even when so-considered, the combination does not suggest the claimed invention. At best, the skilled worker would simply consider Ito's bioluminescent assay as an alternative technique to use in the analysis of the role played by AK, *i.e.*, for measuring the activity of Kahane's pure acetate kinase (AK) preparation. However, Kahane's method of determining the activity of a purified enzyme that has been purposely produced and is known to be present in the analyzed sample does not provide any hint of a method for assessing whether a sample has unknowingly been contaminated with *mycoplasma*.

Particularly lacking in the combination presented in the Office Action, for example, is (1) why a skilled worker presented with Kahane would need to run a control sample and compare the results of that control sample with a second measurement (see

requirements of claim 2 and thus all of its dependent claims and claim 33), and (2) why a skilled worker would use the method of Kahane on a cell culture at all (see claims 25-29, and 45-48) and particularly in a method for treating a cell culture (claim 32).

Kahane provides no motivation to use its assay on any sample that is of unknown composition, *i.e.*, that is not already known to contain acetate kinase. If the sample does not knowingly contain acetate kinase, why would Kahane have any interest in testing it? Only by exercising a hindsight analysis of the claimed invention would a skilled worker see any possible nexus between Kahane's assay and the present invention.

Reconsideration and formal allowance of the pending claims thus are respectfully requested.

Respectfully submitted,

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